

be entitled. Rather, Applicant reserves Applicant's right to pursue such protection at a later point in time and merely seeks to pursue protection for the subject matter presented in this submission.

3. Claims 18 and 19 are amended to correct their dependency. Claim 35 is amended to correct a typographical error.

4. Claim 1 stands rejected under 35 USC § 102(e) as being anticipated by U.S. Patent Application Pub. No. US2002/0156531 ("Felt"). Applicant respectfully disagrees. The Examiner relies on Figures 1-10 and paragraph 0310 of Felt as teaching:

"inserting a catheter into a localized region of said body;
exuding from said catheter a substance capable of perfusing into at least some tissue in said localized region;
allowing said substance to perfuse into a tissue of said localized region;
emitting from said catheter energy of a frequency and in an amount effective to cause a temperature change in said substance; and
contracting said dilatation;
whereby at least some tissue in said localized region is treated."

There is no teaching whatsoever in Felt of a substance capable of perfusing into at least some tissue. Felt describes a method, apparatus and related composition for repair of a tissue site. A curable polyurethane composition is delivered to a tissue site, where it is fully cured to form a permanent and biocompatible prosthesis for repair of the tissue site. (Abstract). Felt's polyurethane composition is formed by the admixture of several parts that result in a liquid that cures very rapidly once delivered to the tissue site to form a discrete structure, a prosthesis, which is distinct from the surrounding tissue (Figure 5). Thus, Felt does not describe a substance capable of perfusing into the tissue at the tissue site because Felt could not employ a substance capable of perfusing into the tissue. If Felt used a substance capable of perfusing into the surrounding tissue, he would not be able to achieve the object of forming an *in situ* prosthesis, because the substance would be absorbed by the tissue, rather than curing and forming the prosthesis. Furthermore, even if Felt employed a substance capable of perfusing into the surrounding tissue, the substance would be prevented from doing so because the substance is not

delivered directly to the tissue site. Rather the substance is delivered into a balloon or mold as shown in Figs. 1 and 3-6. Thus, placing a physical barrier between the substance and the tissue renders it incapable of perfusing into the tissue.

For the reasons discussed above, there is also no teaching in Felt of allowing said substance to perfuse into a tissue of said localized region. Felt instead delivers the curable polymer to a site within a body part, more particularly a bony structure that has been surgically modified to accommodate the prosthesis; e.g. paragraph 0110: "The glenoid fossa is arthroscopically exposed and the residual cartilage is removed by burrs and cutters. Optionally, . . . the humeral head is smoothed and all roughened cartilage surfaces removed. With the patient suitably positioned . . . a curable biomaterial is allowed to flow into the glenoid fossa." Emphasis added. Thus, Felt's flowable material is placed into apposition with the bony tissue. It is not allowed to perfuse into the tissue.

There is no teaching in Felt of contracting a dilatation, which is a disturbance particular to soft tissue. In fact, Felt is overwhelmingly directed to repair of bony and cartilaginous tissue. While Felt appears to propose use of the described device in the manner of an angioplasty catheter to dilate stenotic lesions in blood vessels (para. 0290), there is no mention whatsoever of contracting dilatations. Furthermore, the treatment of stenotic lesions is not described in sufficient detail to enable one having an ordinary level of skill in the relevant art.

Thus, the rejection of Claim 1 under 35 U.S.C § 102(e) is improper. Accordingly, Claim 1 and all Claims depending therefrom are deemed to be allowable.

5. Regarding Claim 3: There is no mention whatsoever in Felt of treating cancerous, engorged, inflamed or infected tissue. Thus, the rejection of Claim 3 under 35 U.S.C § 102(e) is improper.

6. Regarding Claim 5: There is no mention whatsoever in Felt of treating a cyst, tumor or wart tissue. Thus, the rejection of Claim 5 under 35 U.S.C § 102(e) is improper.

7. Regarding Claim 8: There is no mention whatsoever in Felt that the substance includes a saline solution. Thus, the rejection of Claim 8 under 35 U.S.C § 102(e) is improper.

8. Regarding Claims 18 and 19: There is no mention whatsoever in Felt of shrinkage of a lumen or sphincter. Thus, the rejection of Claims 18 and 19 under 35 U.S.C § 102(e) is improper.

9. Regarding Claim 25: There is no mention whatsoever in Felt of avoiding local centers. Thus, the rejection of Claim 25 under 35 U.S.C § 102(e) is improper.

10. Regarding Claim 28: There is no mention whatsoever in Felt of a space-filling balloon having a lumen through it. Thus, the rejection of Claim 28 under 35 U.S.C § 102(e) is improper.

11. Regarding Claim 36: There is no mention whatsoever in Felt of a porous balloon, a microporous balloon, or a balloon with a porous or a microporous membrane. Thus, the rejection of Claim 36 under 35 U.S.C § 102(e) is improper.

12. Claims 20, 23-24 and 30-31 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Felt in view of Guglielmi. In view of the above, the current rejection is deemed to be moot.

13. Regarding Claim 20: Even if the current rejection were not moot, it would be improper because there is no teaching or suggestion in either of the references of shrinkage of engorged or inflamed tissue by removal of lipids or water.

14. Regarding Claim 24: There is no teaching or suggestion in Guglielmi of promotion of epithelial cell growth. While Guglielmi mentions at Col 9, line 6 to line 9 that surface damage to tissue is minimized or avoided, the reference makes no mention of positively promoting epithelial cell growth. Therefore, even if the current rejection were not moot, it would be improper, because one skilled in the art, considering Felt's teachings, having the motivation of promoting epithelial cell growth, would not be lead to Guglielmi, because Guglielmi teaches nothing about promoting epithelial cell growth

CONCLUSION

In view of the foregoing, the Application is deemed to be in allowable condition. Therefore, Applicant earnestly requests the Examiner to withdraw all rejections, allowing the Application to pass to issue as a United States Patent. Should the Examiner have any questions regarding the Application, he is urged to contact Applicant's attorney at the telephone number given below.

Respectfully submitted,



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